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PATENT SPECIFICATION

DRAWINGS ATTACHED

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COMPLETE SPECIFICATION

Improvements in and relating to Extreme Hyperthermy

I, MANFRED VON ARDENNE, of 7, Zeppelinstrasse, 8051, Dresden-Weisser Hirsch, Germany, a German Citizen, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement: —

The present invention is concerned with a device for performing extreme hyperthermy for therapeutic purposes, more particularly for the treatment of malignant tumours.

It has already been proposed to use extreme hyperthermy for the treatment of tumours in the human body, suitably in conjunction with multiple chemotherapy, i.e. a method employing a combination therapy carried out in a number of stages. In this connection, use is made of the fact that the greatest proportion of cancer cells are destroyed at a body or tumour region temperature of 41—44°C. In a further treatment step, which follows either directly after hyperthermy or is carried out after an interval of several days, the few remaining cancer cells or reduced resistance are chemotherapeutically treated by various known methods.

It is known that by means of hyperthermy at a temperature of 44°C. for a period of 30 to 45 minutes, followed by multistage cancer chemotherapy, about 99% of the cancer cells can be destroyed.

It is further known that a general hyperthermy of the human body can be performed for therapeutic purposes, this being effected either by inducing fever or by the external application of heat. For inducing fever, medicaments or biological means are used, while external heating is generally performed by means of a hot bath. The latter is preferable to other means, such as hot air, radiation or high frequency, for heating the whole body since it offers the most advantages, in particular, a rapid, readily-controllable and uniform heating.

Since hyperthermy in humans has hitherto not generally exceeded the physiological fever temperatures, in the case of the warm bath treatment, the patient is either placed in a sitting position or laid in an inclined position in the water so that the head remains above the water and can, if necessary, be cooled.

The body temperature is measured by means of mercury thermometers or other measuring instruments, usually in the mouth or rectum.

For the additional supervision of the condition of the patient, various known devices, such as electrocardiographs, may be used. With extreme hyperthermy at a temperature of 42 to 44°C. or possibly higher, in extensive vasodilatory relaxation of the blood vessels takes place so that the patient passes into a state of peripheral collapse in which the blood circulation becomes blocked in the deeper situated parts of the capillary region. With the patient disposed with the head raised, as has hitherto been the practice in conventionally used baths, there is the likelihood of a dangerous blood deficiency in the heart and brain which, even at normal body temperatures, but still more in the condition of extreme hyperthermy, could represent a serious danger for the patient. For this reason, the patient must be disposed absolutely horizontally in the heating bath. By use of the known technique, such a horizontal disposition is only possible if the head is immersed below the water. Such a process is naturally not acceptable, especially since a heating of the brain to the hyperthermy temperature is unavoidable.

The provisions for checking the body temperature in the known arrangements are not suitable for allowing measurements of body temperature at various regions within

the heated tissue, for example in a tumour. Furthermore, the temperature sensing implements are too large to be introduced into the tissue.

Known methods for measuring the physiological condition of the patient, particularly the heart action and circulation system, do not permit optimum supervision so that early recognition of an oncoming crisis is not possible because, by taking periodic electrocardiograms and by counting the pulse rate with a watch, alteration tendencies of the heart beat frequency cannot be immediately recognised and, in addition, warning devices have hitherto not been provided which respond immediately to any change in the heart rhythm.

It is an object of the present invention to avoid the disadvantages of the known techniques of extreme hyperthermy in humans for therapeutic purposes, more particularly for the treatment of malignant tumours, such as cancer.

Since, at the present time, about 20% of all humans die from cancer and this figure is continuously increasing, the present invention represents an important contribution to the art of medical treatment.

The problem forming the basis of the present invention is to provide a device which enables a patient to be disposed horizontally in a warm bath in such a manner that the head remains free and can be separately cooled and that the patient can be given supplementary local underwater heating at a particular body region by means of high frequency energy.

Advantageously, the device is combined with special control means so that the extreme hyperthermy treatment can be carried out with a high degree of safety and therapeutic effect for the patient. Such control may be carried out by the use of a device for monitoring the blood circulation system, together with a temperature measuring device having a sensing member suitable for the direct insertion into the tissue.

Thus, according to the present invention, there is provided a device for performing extreme hyperthermy on humans at a body temperature of 41 to 42°C., comprising, in combination, a double chamber bath, a short-wave heating means, temperature measuring probes and a monitoring or control system. The double chamber bath permits a heating of the patient's body, while simultaneously cooling the head and neck or upper thoracic region, with the patient disposed horizontally in the bath. For locally heating the body to 44°C. in the region of a tumour, their is used an immersible short wave heating means. Temperature probes are inserted into the tumour tissue and other tissue sections for monitoring, together with suitable means for supervising the heart action and blood circulation of the patient and, in particular, continuously to register the heart beat frequency, in combination with an automatic warning system for signalling an approaching crisis.

According to the present invention, a dividing wall is provided between the two chambers of the bath, this dividing wall being designed elastically to surround the neck or upper thoracic region of the patient in a water-tight manner and adapted to fit different patients. Furthermore, for opening and closing, the dividing wall is provided with suitable means, for example a zip, and is constructed in such a manner as to permit the immediate removal, without hindrance, of a patient in a critical condition.

The double chamber bath of the present invention is designed to receive the body of the patient in one chamber, through which warm water flows so as to immerse the body of the patient completely. In the second chamber, which contains cold water, the head of the patient is disposed in the water in such a manner that the face of the patient remains above the water level. Alternatively, ice packs may be used for cooling the head and neck region of the patient, in which case the second chamber need not contain cold water.

An inlet means and an outlet means for warm water are provided in the body chamber, together with means for keeping the water level constant. Furthermore, a drain with an automatically controllable valve is provided in this body chamber to allow the rapid discharge of warm water in case of a crisis. Similarly, the chamber for the head of the patient has an inlet means and an outlet means for cold water, as well as a means to keep the cold water level constant.

A grating, the elevation of which is adjustable, is provided in the double chamber bath, this grating being covered with a perforated padding in order to provide a soft bedding for the head and body of the patient.

For the supplementary under-water local heating of a tumour region to 44°C. by high frequency, there is used an immersible heating means, for example, a water-tight short wave device containing an eddy-current coil system, the heating means being surrounded by a ferrite sleeve which is open towards the patient in order to increase its effectiveness. Depending upon the desired penetration depth of the short waves, coil units of different diameters can be used.

Measurement of the temperature is effected in a tumour region or in other tissue regions by means of thermocouples which have been welded together by lasers and which are embedded in readily insertable, very thin cannulae. The body temperature of the

patient can be measured either rectally or sublingually.

According to the present invention, automatic control devices are provided to maintain the water levels and temperature at a constant value, and furthermore, in combination with the monitoring apparatus, to actuate warning devices in the event of a crisis which, for example, instantly effect the rapid discharge of the warm water from the bath chamber for the body of the patient.

With the aid of the device according to the present invention, with a reduced risk to the patient, there can be obtained an extreme hyperthermy of a degree which has not hitherto been possible in a reproducible form. As a result of the reproducibility, renewed treatment can be effected at an interval of one to two years, if the diseased tissue has grown again.

For a better understanding of the present invention, reference will now be made to the accompanying drawing, which is given by way of an example and which presents a diagrammatic view of a hyperthermy treatment apparatus in accordance with the present invention.

The apparatus of the present invention comprises a double chamber bath 1, mounted on a hydraulic elevating device 2, this both 1 containing a chamber 9 for the body of the patient and a chamber 15 for the head of the patient. The patient 5 is secured by means of belts 6 to a grating 3, for example of metal, covered with a perforated padding 4. The elevation of the grating 3 can be adjusted relative to the water level in the double chamber both 1, the two chambers of which are divided by means of a dividing wall 7 which bears against the neck region of the patient 5 in a water-tight manner. In addition, there is provided an adjustable foot abutment 8 which pushes the patient against the dividing wall 7. In case of an emergency the design of the dividing wall 7 allows the patient 5 to be quickly taken out of the double chamber both 1 by opening a zip closure (not shown) in the separating wall 7 or by removing it entirely after the water has been partially drained from the body chamber 9.

The body chamber 9 is provided with a hot water supply pipe 10, a hot water discharge pipe 11, an overflow 12 for maintaining constant the water level and a rapid emergency drain pipe 13 in case the patient has to be quickly removed from the bath. The high water level 14 of the chamber 9 completely covers the body of the patient 5. The water temperature should be higher than the body temperature of the patient, for example 45°C., in order to effect proper heating.

The head chamber 15 is provided with a cold water inlet 16, a cold water discharge pipe 17 and an overflow 18 for maintaining constant the water level. The relatively low water level 19 in the head chamber 15 leaves the face of the patient 5 free. The neck of the patient can, if desired, also be cooled by an ice pack 20 so that the blood vessels, through which blood flows to the brain, can be cooled. The head chamber 15 can also be used without water therein. When used without water, it acts as a receiver for any water leaking out of the body chamber 9 or for water produced by the melting ice pack 20.

The supplementary local heating of a tumour region is effected by a submersible short wave heating device 21 of water-tight design, which is surrounded by a ferrite sleeve 22 open towards the patient 5. Depending upon the patient being treated, one or several short wave heating devices 21 can be employed. The supply of energy to the short wave heating device is preferably effected with an alternating voltage at a frequency of 20 to 25 megacycles per second but it is also possible to use frequencies of about 13 megacycles per second. The ferrite sleeve 22 acts in such a way that a large proportion of the high frequency field lines are directed into the body tissue.

Temperature supervision is effected by a rectal temperature sensing device 23 and a sub-lingual sensing device 24 and also by very thin thermocouples 25 inserted directly into the tissue, for example into the tumour region 26. These thermocouples 25 can be produced by laser welding techiques and embedded in thin cannulae. By means of the temperature measurements effected at various points of the patient's body 5 and in conjunction with the control system provided, the desired temperatures can be automatically controlled and kept at a constant level.

Supervision of the condition of the patient is continuously effected by means of an electrocardiotachograph 27 connected to electrodes 28 and 29 placed on the patient 5 or by other sensing arrangements, more particularly so as to provide a continuous recording of the momentary heart beat frequency in connection with a warning device contained in the supervision arrangement, the warning device responding to conditions of cardiac arrest, bradycardia, tachycardia and arrhythmia.

WHAT I CLAIM IS:—

1. A device for performing extreme hyperthermy on humans, while horizontally disposed, at a body temperature of 41 to 42°C., comprising a water bath divided into two chambers by a dividing wall, one chamber serving for heating the body of the patient and the other chamber being adapted for cooling the head and neck region of the patient, together with a water-tight short wave heating means immersible in the water for heating

the region of a tumour on the patient to 44°C. under water, at least one measuring probe for measuring the temperature in a tumour region or other tissue region and monitoring means for supervising the heart action and the blood circulation of the patient.

2. A device according to Claim 1, wherein the heart monitoring means comprise means for continuously recording the heart beat frequency and for monitoring the blood circulation system, together with an automatic warning device to indicate the onset of a crisis in the patient.

3. A device according to Claim 1 or 2, wherein the dividing wall elastically surrounds the neck or upper thoracic region of the patient in a water-tight manner and is adapted to fit different patients, said dividing wall being provided with closure means which can be rapidly opened in case of an emergency.

4. A device according to Claim 3, wherein the rapidly opening closure means in the dividing wall is a zip.

5. A device according to any of the preceding claims, wherein the chamber of the bath in which is disposed the body of the patient has a water level which is sufficient completely to cover the body of the patient, while the chamber of the bath receiving the patient's head has lower walls and a lower water level in order to keep the face of the patient out of the water.

6. A device according to any of the preceding claims, wherein the chamber intended to receive the body of the patient is provided with a hot water supply connection, a hot water discharge connection and means for maintaining the water level constant and wherein the chamber intended for receiving the head of the patient is provided with a cold water supply connection, a cold water discharge connection and an arrangement for maintaining the water level therein constant.

7. A device according to any of the preceding claims, wherein an automatically controllable valve is provided, together with a rapid emergency water discharge outlet, in the chamber receiving the body of the patient.

8. A device according to any of the preceding claims, wherein a platform, the elevation of which is adjustable, is provided on the bottom of the bath for supporting the patient in a horizontal position.

9. A device according to Claim 8, wherein the platform comprises a supporting grating on which is disposed an apertured mattress.

10. A device according to any of the preceding claims, wherein the water-tight short wave heating means comprises an eddy-current coil system having a ferrite sleeve which is open towards the patient.

11. A device according to any of the preceding claims, wherein the probe for measuring the temperature in the region of a tumour consists of small thermocouples, preferably laser-welded, and incorporated in very thin tubes or cannulae.

12. A device according to any of the preceding claims, wherein there is provided an automatic control for keeping the water level and water temperature constant, together with a monitoring system which, in case of an impending crisis in the patient, operates a warning device and initiates other measures, for example, the rapid discharge of the water from the body chamber of the bath.

13. A device according to Claim 1 for performing extreme hyperthermy, constructed and arranged substantially as hereinbefore described with reference to and as illustrated in the accompanying drawing.

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1 SHEET This drawing is a reproduction of the Original on a reduced scale